

CHAPTER 4

4.0 EVALUATING THE BASELINE HHRA

4.1 INTRODUCTION

This chapter presents the conceptual and technical objectives for evaluation of a baseline HHRA²⁰, and the minimum content expected to be included when evaluating a BRA. The BRA provides an objective technical evaluation of the potential health impacts posed by a site and should not incorporate policy, management, and other nontechnical factors. The BRA should be clear about the approaches, assumptions, limitations, and uncertainties inherent in the evaluation to enable the risk assessor and risk manager to interpret the results and conclusions appropriately. The BRA is used by the risk manager, in conjunction with regulatory, policy, feasibility, schedule, budget, and value of resources considerations, to determine the appropriate response actions at the site.

The BRA is one component of overall site investigative and remedial activities and, as such, should be developed with an understanding of how it is supported by preceding components of site activities, such as sampling and analysis, and how it supports and shapes follow-on components, such as remediation. Although the BRA is performed to achieve several specific objectives (such as describing potential health risks), it may also be needed to support other general response objectives.

This chapter is not intended to be a step-by-step instruction manual for developing a BRA, rather, it is a guide for reviewing and evaluating BRAs. Adequate guidance is provided in other resources for preparing a BRA, and is referred to below and throughout the chapter. This chapter discusses the important components of a BRA, highlighting where up-front planning and professional judgment are needed, and

identifying the factors that should be present in a well-constructed risk assessment.

The methodology presented in this chapter has largely been developed by the EPA for activities undertaken under CERCLA. The primary guidance documents that form the basis for the discussion on BRA methodology are listed below. Of these guidance documents, RAGS (USEPA, 1989j) provides the general overview and structure of the risk assessment process. As noted earlier, a thorough understanding of RAGS is prerequisite to the USACE process, and redundancies will not be found in this guidance. This guidance will, however, provide the details necessary to focus investigations toward site closeout and provide USACE procedures relative to performance and evaluation of a site-specific BRA. Appendix A presents additional selected OSWER directives and EPA regional guidance.

- *Risk Assessment Guidance for Superfund: Human Health Evaluation Manual (Part A)* (RAGS) (USEPA, 1989j).
- RAGS Part B (USEPA, 1991d).
- RAGS Part C (USEPA, 1991e).
- RAGS Part D (USEPA, 1998a).
- *Exposure Factors Handbook* (USEPA, 1997c).
- *Guidance for Data Useability in Risk Assessment (Part A)* (USEPA, 1992h).
- *Guidance for Data Useability in Risk Assessment (Part B)* (USEPA, 1992k).
- Applicable Directives from EPA's OSWER ("OSWER Directives") (ongoing issuance), including:
 - *Guidance on Risk Characterization for Risk Managers and Risk Assessors* (USEPA, 1992d).
 - *Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors* (USEPA, 1991b).

²⁰ For the purposes of this text, Baseline HHRA and BRA can be used interchangeably. BRA will be used here to avoid confusion with established EPA guidance for HHRA (EPA, 1989i). It is understood that the evaluation of potential environmental risks, or ERA, is an integral part of the BRA.

- *Supplemental Guidance to RAGS: Calculating the Concentration Term* (USEPA, 1992j).
- *Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities* (USEPA, 1994c).
- Various subject-specific guidance developed to support specific aspects of risk assessment, such as:
 - *Superfund Exposure Assessment Manual* (USEPA, 1988d).
 - *Dermal Exposure Assessment: Principles and Applications* (USEPA, 1992c).
 - *Guidelines for Exposure Assessment* (USEPA, 1992i).
 - *Guidance for Data Useability in Risk Assessments (Parts A and B)* (USEPA, 1992h,k).
 - *Laboratory Data Validation, Functional Guidelines for Evaluating Inorganics Analyses* (USEPA, 1994b).
 - *Laboratory Data Validation, Functional Guidelines for Evaluating Organics Analyses* (USEPA, 1994a).
 - EM 200-1-1, *Validation of Analytical Chemistry Laboratories* (USACE).
 - EM 200-1-3, *Requirements for the Preparation of Sampling and Analysis Plans* (USACE).
 - EM 200-1-6, *Chemical Quality Assurance for HTRW Projects* (USACE).

4.2 SUMMARY AND REVIEW OF ANALYTICAL DATA.

The quality of a BRA is directly dependent upon the quality of the chemical data applied. Regardless of how well other components of the BRA are performed, if the quality of the data is poor or the data do not accurately reflect the site contamination or the appropriate types of exposures, the BRA will not provide an adequate description of potential health effects posed by the site. Therefore, it is imperative that the types of data used in an assessment be carefully evaluated as well as properly used.

4.2.1 Historical Data Review. In some instances, historical data are available and can be used, in whole or in part, with or without supplemental data, to assess potential health risks associated with the site. Often, the data have been collected for purposes other than for use in a BRA and, thus, may not be appropriate for inclusion in a BRA. Prior to inclusion in a BRA, these data must be reviewed for useability.

4.2.2 Guidance. This chapter highlights several factors that should be considered when evaluating data collected specifically for a BRA, or when reviewing existing data to determine its useability. Much of the information presented herein has been obtained from the following documents:

4.2.3 Evaluation of Data Quality. An evaluation of data quality should examine five broad categories, each discussed in the following paragraphs. The risk assessor must be aware of the important factors within each category to enable him or her to judge whether the data are appropriate for inclusion in the BRA, as specified in the DQOs. These are:

- Data collection objectives.
- Documentation.
- Analytical methods/QLs.
- Data quality indicators.
- Data review/validation.

4.2.3.1 Data Collection Objectives. The objective of the data collection program should be re-examined as part of data evaluation to determine whether the type and scope of analyses were appropriate for risk assessment purposes, and whether supportive information (such as QA/QC protocols) is available. Optimally, all data available for a BRA will have been collected with consideration of specific minimum requirements (DQOs). These data should be evaluated in terms of the attainment of these objectives or minimum requirements. Each factor specified as a minimum requirement or objective should be re-examined to determine the degree to which

these requirements were attained during sampling and analysis.

4.2.3.2 Documentation. The collection and analysis of site media have been adequately documented to demonstrate that the samples were collected, handled, and analyzed according to the DQOs and/or minimum requirements specified for BRA data. Documentation on adherence to these minimum requirements should be available for review by the risk assessor.

4.2.3.3 Analytical Methods and QLs. The analytical methods, DLs, and QLs applied to BRA data collection should be specified as part of the minimum requirements prior to the data collection. Once data results are available, the analytical methods used and DLs attained should be re-examined to identify any deviations from the minimum requirements, and the impact of that deviation upon data useability.

4.2.3.4 Data Quality Indicators. Six data quality indicators (precision, accuracy, representativeness, completeness, comparability, and sensitivity) need to be considered when reviewing chemical analytical results. The assigned data evaluator/validator should examine these factors as part of the formal data evaluation procedures. However, it is important for the risk assessor to understand the terms and meaning in order to understand the data evaluation reports and how they affect the useability of the data.

4.2.3.5 Data Review/Evaluation.

4.2.3.5.1 Review and evaluation of chemical data can be performed at different levels and depths, depending on the desired use of the data. Prior to inclusion in a BRA, site data should undergo an evaluation process. Data evaluation should be performed by a chemist or other qualified individual. The risk assessor need only know that the data have been reviewed according to acceptable protocols, and all data have been appropriately qualified. Summary reports from the data evaluation will inform the risk assessor of any variations or deviations from accepted protocols.

4.2.3.5.2 Different analytical protocols have different data evaluation requirements. In addition, different protocols may use different qualifiers or

criteria for evaluating data. The risk assessor needs to be clear about the appropriate evaluation requirements for the protocols applied to assure appropriate interpretation of the data.

4.2.3.6 Data Summary/Segregation of Data. General data that have been identified as acceptable for use in a BRA should be summarized in a manner that presents the pertinent information to be applied in the BRA. Any deviations from the DQOs or minimum requirements should be identified, and the potential effects upon the BRA described in the assessment. Any data that have been rejected as a result of the data evaluation should be identified, along with a reason for their rejection. At this point in the BRA, all appropriate site data identified as acceptable by the data evaluation process should be combined for each medium for the purposes of selecting COPCs for the site, as discussed in Paragraph 4.3. However, this does not mean that all available data are to be combined. "Appropriateness" of data should take into consideration the area of exposure to be assessed.

4.3 SELECTION OF COPCs

4.3.1 Objectives. The objective of selecting COPCs for the BRA is to identify a subset of chemicals detected at the site that could pose a potential health risk to exposed receptors. The selection process is needed for several reasons:

- Not all chemicals detected at a site are necessarily related to the site. Some may be naturally occurring, a result of anthropogenic activities or of chemical use in offsite areas.
- Some chemicals may be a result of inadvertent introduction during sampling or laboratory analysis.
- Not all chemicals detected at a site are present at concentrations high enough to pose a potential exposure or health threat, or may be trace elements present at health-protective concentrations.

The chemical selection process is performed on the data that have been identified as useable by the data evaluation process. COPC selection involves evaluation of these data using a number of criteria that are designed to identify those chemicals that are not appropriate to retain as COPCs. Through an exclusion process, the COPCs are

selected from the list of chemicals analyzed in site media. The outcome of the selection process is a list or lists of chemicals in site media that are later assessed quantitatively in the BRA.

4.3.2 General Considerations. Two general factors should be considered before applying the chemical selection process. These factors allow the risk assessor to select the most appropriate data to include in the assessment.

- What is the exposure area?
 - Not all chemical data collected from site media represent those to which a receptor is necessarily exposed. When selecting COPCs, the potential receptors, exposure pathways, and exposure routes identified in the preliminary CSM should be examined. The preliminary CSM will identify where exposure is expected to occur (onsite, offsite, to surface soils, to subsurface soils, through ground water, by direct contact, etc.). This information is then used to help identify the media and locations where assessments will be directed and COPCs identified for each pathway of concern.
 - A distribution analysis of the chemical presence at the site should be conducted. This examination would differentiate between impacted areas and nonimpacted areas which is particularly useful at very large sites. The distributional analysis can be a statistical evaluation or performed qualitatively. The distributional analysis may identify the whole site as the exposure area or only subunits of the site as the exposure area.
- Are the chemical data appropriate?
 - Even with high quality, useable data, the form of the chemical or sampling technique should be examined for relevance for exposure. For example, unfiltered ground water data may not be relevant to exposures if all water withdrawn from an aquifer for potable purposes is normally filtered prior to consumption. Data composited from multiple locations and depths may also not be relevant to exposures if

exposure to these locations and depths is not plausible.

4.3.3 Selection Criteria/Methodology. Criteria that can be applied to determine whether a chemical should not be retained as a COPC are:

- Nondetection.
- Comparability with background concentrations.
- Non-site-relatedness.
- Role as an essential nutrient and presence at health-protective levels.
- Limited presence.

Each criterion is discussed further in the following paragraphs.

4.3.3.1 Nondetection. Chemicals analyzed for but not detected in any sample of a site medium should not be included as COPCs for that medium. Care must be taken when evaluating analytical results in which a very high DL was attained, since a significant concentration of a chemical may be “masked” due to the elevated QL. Although a quantitative estimate of the chemical's concentration value is unavailable in such a case, the chemical may be assessed qualitatively to determine if it is present in other site media (if so, EPA recommends utilizing one-half of the SQL as a proxy concentration) or re-sampling may be indicated.

4.3.3.2 Comparability with Background Concentrations.

4.3.3.2.1 Some chemicals detected in site media may be naturally occurring or present as a result of ubiquitous or offsite chemical use. Therefore, it is appropriate to exclude them from the risk assessment. Background samples are segregated from the site data, and are used exclusively to identify non-site-related chemicals.

4.3.3.2.2 Acquisition of site-specific background information is always preferable to regional or national values when examining site-relatedness and comparability to background concentrations. Literature values describing regional or national background ranges for chemicals in soil, ground water, surface water, and

sediments may be used, but only if site-specific background information is unavailable. Regional or national ranges are relatively insensitive and can lead to misinterpretation of the data.

All USACE Risk Assessments Shall Include a Statistically Robust, Significant, and Defensible Set of Background Concentrations

Background values should be expressed as the 95% CL on the mean. Chemicals properly applied to the environment according to their intended use (i.e. pesticides and herbicides) shall not be considered as contaminants, but should be considered as a part of the background. In industrial areas, normal concentrations of anthropogenic contaminants shall be considered as part of the background.

4.3.3.2.3 Determination of comparability with background can be accomplished in several ways, depending on the amount of data available. Two methods that are available are statistical evaluation and numerical comparison.

- A statistical evaluation is best utilized when a sufficient number of site and background samples are available to test the null hypothesis that there is no difference between the site and background mean chemical concentrations. This approach can be used when the risk assessor has defined the minimum requirements for background and site sample numbers and sampling design. Several statistical tests are available with which to determine whether the two data groups, background and site, are comparable. Texts on statistics, such as Gilbert (1987), should be consulted for tests applicable for use in specific site conditions. The selection of test depends upon the distribution of the data (normal, non-normal), whether nondetected values are included, the number of samples, and perhaps (depending on the test) other factors. This is the most rigorous method of determining comparability.
- Numerical comparisons can be made when the background data are more limited in number,

making a statistical comparison less meaningful. This approach may be useful when historical data with limited background samples are being used, or when the minimum requirements for BRA data collection have not been met and less than optimal numbers of background sample results are available. The following comparisons can be made:

- Comparison of mean site concentration to two (USEPA, 1995d) or three (USEPA, 1992a) times the mean background concentration.
- Comparison of range of detected concentrations in both data sets.

4.3.3.5 Chemical Distribution. The physical distribution and frequency of detection of a chemical in a site medium or exposure area can be used to refine the list of COPCs. The premise behind this criterion is that a chemical with a limited presence in a medium or exposure area does not pose as great a potential health risk as do chemicals more frequently detected. The distribution of the chemical presence in a site or exposure area should be examined by identifying where the chemical was and was not detected and its frequency of detection. If this evaluation indicates that the distribution of the chemical is low, i.e., it is detected in only one or a few locations, it may be reasonable to exclude it as a COPC, or to select the chemical as a COPC for a smaller exposure area of the site. This screening should be performed in conjunction with the toxicity screening to assure that chemicals representing risks to receptors are not eliminated unnecessarily from the list of COPCs.

4.3.4 Presentation of COPCs. The conclusion of the chemical selection process is a subgroup of chemicals that are selected as COPCs and which will be used in the BRA. Tables should be developed segregating the COPCs selected for each medium and/or exposure area. All chemicals that were removed from consideration should be identified, with an explanation of the reason for their exclusion.

4.4 EXPOSURE ASSESSMENT

The purpose of the exposure assessment of a BRA is to estimate the nature, extent, and magnitude of potential exposure (or site-specific dose) of receptors to COPCs that are present at or migrating from a site, considering

both current and plausible future use of the site. Several components of the exposure assessment have previously been characterized during earlier stages of the site investigation for the purposes of developing the CSM and focusing investigative activities. These components include identification of potential receptors, exposure pathways, and exposure areas. These preliminary characterizations were based upon early and often incomplete information that now must be clarified in light of the information obtained during the RI.

4.4.1 Refinement of the CSM. The CSM is a representation of certain aspects of the exposure assessment. Its earlier formulation was based upon assumptions regarding chemical presence and migration, which now should be verified and revised (if necessary) with information collected during the site investigation.

4.4.2 Characterization of the Exposure Setting.

4.4.2.1 The objective in describing the exposure setting is to identify the site physical features that may influence exposure for both current and future scenarios. While each site will differ in the factors that require consideration, some of the more common factors are listed below and discussed briefly. Examples of how the factor may influence exposures are also provided.

- **Geology.** The land type and forms may influence exposure in various ways. For example, the topography of the area can influence the direction of chemical migration to offsite areas. The presence of surface water bodies may indicate potential exposures through recreational or potable use of the water or through the consumption of aquatic organisms (i.e., fish and shellfish).
- **Hydrogeology.** The number, types, and characteristics of aquifers (depth, salinity, use, ground water flow direction, and velocity) should be examined to evaluate whether exposure to ground water is possible and, if so, where, when, and to whom.
- **Climate.** The temperature and precipitation profile of the area may limit the frequency of exposure (e.g., frozen surface water bodies, extent of outdoor activities) as well as influence the extent of

chemical migration (e.g., rates of volatilization and infiltration).

- **Meteorology.** Wind speed and direction may influence the entrainment of soil particles and the extent of transport and dilution of air contaminants.
- **Vegetation.** The extent of vegetation may influence the availability of soil for dermal, ingestion, or inhalation exposure and the potential for exposure through the food chain.
- **Soil type.** The type of soil (e.g., grain size, organic carbon, clay content) may influence soil entrainment, the degree of chemical binding, and leaching potential.

4.4.2.2 Description of the site setting in the exposure assessment should involve obtaining more specific, in-depth information than obtained during the preliminary CSM development and should be supplemented by data collected during the RI. Descriptions of portions of the exposure setting may have been discussed in other portions of the site report, and need only be referenced in this portion. However, characteristics of the exposure setting that are specific to potential exposures should be presented.

4.4.3 Identification of Exposure Pathways and Intake Routes.

4.4.3.1 An exposure pathway is the physical course a chemical takes from the source to the receptor exposed. Chemical intake is how a chemical enters a receptor after contact, e.g., by ingestion, inhalation, or dermal absorption (USEPA, 1992i). These two components are considered together in this paragraph to identify potential exposures. A complete exposure pathway consists of the following elements:

- A source and mechanism of chemical release.
- An intermedia transport mechanism (if the exposure point differs from the source).
- Migration pathway.
- A receptor group who may come into contact with site wastes.

- An exposure route through which chemical uptake by the receptor occurs.

As the field investigation has been accomplished, the chemical data can now be evaluated to determine the completeness of the pathways identified in the CSM.

4.4.3.2 Potential Exposure Routes. When performing the exposure assessment, the following exposure routes should be examined regarding the completeness of the pathway.

- Ingestion of water.
- Dermal contact with water.
- Ingestion of soil or sediments.
- Dermal contact with soil or sediments.
- Inhalation of both vapor phase chemicals and particulates.
- Exposure to biota (i.e., Ingestion of plant or animal species).

4.4.4 Identification of Potential Receptor Populations. The identification of potentially exposed receptor populations (completed during the TPP process) involves defining the current and anticipated future use of the site, and identifying the current and future activities of receptors on or near the site. At this point in the assessment, it is necessary to revisit those assumptions and evaluate whether any modifications in the preliminary assumptions are required. Chemical and physical data collected either onsite or offsite may indicate that certain receptor groups are not at risk, or that new receptors may need to be evaluated.

Future Land Uses for Risk Assessment Purposes and for Development of RAOs Shall be Land Uses that are Reasonably Expected to Occur at the Site or Facility

Property that is currently used for industrial or commercial purposes at facilities will most likely be used for those same purposes in the future. Even in closure situations, the land use frequently stays the same. Residential land use should not be the default land use unless it is reasonably expected to occur. It is very important the future land use be discussed early with regulators, city/county zoning officials, and the public.

4.4.5 Quantitation of Exposure (Intake or Dose).

Chemical intakes, or doses, are estimated for exposures that could occur from complete exposure pathways for each receptor group. The exposures are quantified with respect to the magnitude, frequency, and duration of exposure to derive an estimate of chemical intake or site-specific dose. Intakes of chemicals are estimated by combining two general components: the chemical concentration component (or exposure point concentration) and the intake/exposure factors component. Estimation of the exposure point concentration, selection of intake and exposure factors, and specific methods of combining them mathematically are presented below.

4.4.5.1 Estimation of Exposure Point Concentrations. Exposure point concentrations represent the chemical concentrations in environmental media that the receptor will potentially contact during the exposure period. They may be derived from either data obtained from sampling or from a combination of sample data and fate and transport modeling, both of which are described below.

4.4.5.1.1 For current (and perhaps some future) exposure scenarios where the current site data are anticipated to be reasonably reflective of exposure point concentrations over the exposure period, the exposure point concentration can be directly derived from site data. For future (and perhaps some current) exposure scenarios, where current site conditions are not anticipated to be

representative of exposure point concentrations over the exposure period, some form of fate and transport modeling or degradation calculations should be applied to derive these concentrations. The available data need to be examined critically to select the most appropriate data to describe potential exposure.

4.4.5.1.2 Many fate and transport models are available with which to predict exposure point concentrations from existing site data. These models are presented in other references and include the following:

- *Superfund Exposure Assessment Manual* (USEPA, 1988d).
- *Air/Superfund National Technical Guidance Study Series (Volumes I - V)* (USEPA, 1989a, 1990e, 1992o, 1993c, and 1995b).
- *A Workbook of Screening Techniques for Assessing Impacts of Toxic Air Pollutants* (USEPA, 1988h).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-water Models* (USEPA, 1988e).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models* (USEPA, 1987a).
- *Rapid Assessment of Exposure to Particulate Emissions from Surface Contamination Sites* (USEPA, 1985).
- *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions* (USEPA, 1990b).

4.4.5.1.3 The type of model and level of effort expended in estimating exposure point concentrations with a model should be commensurate with the type, amount, and quality of data available. In general, it is best to begin with a model that employs simplified assumptions (i.e., a “screening level” approach) and determine whether unacceptable health risks are posed by the exposure point concentration estimated by this approach. If so, a more complex model that applies less conservative assumptions should be used to then derive the exposure point concentrations.

A Minimum of Two Risk Estimates Should be Presented for Each Land Use Scenario: the RME and the CT.

The goal of the BRA is to provide information on potential risks presented by contamination for risk managers to make informed decisions regarding future action. The risk manager needs more information than just worst case to make a good risk management decision. Multiple exposure scenarios within a land use paradigm should be used in the risk assessment to provide the risk manager with information relative to ranges of the perceived risks.

In order to describe a range of potential exposures presented by a site, the BRA should assess more than one potential exposure scenario. Use of a single expression of potential health risks does not provide information on the possible range of health risks, and does not allow the risk manager to evaluate the “reasonableness” of the estimate. Current risk assessment guidance suggests assessing an exposure scenario that represents the high end of the risk distribution, relating to a 90th percentile exposure (often referred to as an RME scenario), and a scenario which more closely describes an average exposure (or CT) (USEPA, 1-992d). Presentation of both (and perhaps additional) scenarios provides information about the range of potential risks.

4.4.5.1.4 Numerous sources are available to select appropriate intake and exposure factors for use in a BRA (see Section 4.1 for the primary EPA guidance documents). In addition to these general references, some EPA regional offices and state environmental or health agencies have developed exposure risk assessment guidance to supplement the EPA Federal guidance.

4.4.5.1.5 Some of the EPA documents provide ranges of values for intake and exposure factors, while others present values intended to represent a specific exposure. For example, the *Standard Default Exposure Factors* (USEPA, 1991b) was developed as guidance only, and the values are intended to be used when site-specific information is not available. EPA encourages the use of site-specific data so that risks can be evaluated to more closely reflect site-specific exposures. Default values

should be used to calculate a high end exposure only when there is a lack of site-specific data or alternate values cannot be justifiably supported.

The Exposure Assessment of a BRA Shall Utilize Site-Specific Frequencies and Durations Whenever Possible.

Where possible, the BRA should use site-specific parameters for input into the risk algorithms. By the use of these parameters, the BRA will be tailored to the actual expected exposures. Additionally, anticipated ranges of values may be used when the BRA utilizes probabilistic methods.

4.4.5.1.6 All values that are used in estimating chemical intake should be clearly presented in the assessment, the source of the value should be identified, and the rationale for using the value provided.

4.4.5.2 Calculation Methodology.

4.4.5.2.1 RAGS identifies general intake equations for each exposure pathway and should be consulted when performing the intake assessment. Some overall assumptions in the use of these equations are presented in the following paragraphs.

4.4.5.2.2 The intake equations developed by EPA for the ingestion and inhalation pathways do not contain a factor to account for bioavailability and, therefore, may predict an intake higher than one that would occur in actual circumstances. By not including a factor to consider bioavailability, it is assumed that 100 percent of the chemical detected in the medium is bioavailable. Modifications may sometimes be made to these intake equations to account for this factor, if the appropriate information is available.

4.4.5.2.3 Bioavailability refers to the ability of a chemical to be "available" in the body to interact and have an effect. There are many aspects to bioavailability; however, the type most of concern to BRAs is the ability of the chemical to be absorbed into the body. Although the medium in which the chemical is contained may be contacted, the chemical may not be

absorbed for a number of reasons, including the chemical form, competition with other factors (e.g., food in the stomach), damage of the organ (e.g., stomach, lung), effect of the medium in which the chemical is contained, and others. Many of these cannot be reliably addressed in a BRA; however, two of these can, the chemical form and the effect of the medium on absorption.

4.4.5.2.4 The form of the chemical can affect the degree of absorption into the body. This factor is most important for chemicals that form compounds (such as metals and cyanide) and chemicals that exist in different valence states (again, some metals). For example, soluble compounds of metals such as barium sulfate are readily absorbed through the stomach, whereas insoluble forms such as barium carbonate are usually not absorbed. Usually, when environmental media are analyzed, chemicals are reported as an isolated entity (e.g., barium), and no information is provided on valence state or compounds that existed in the medium. However, if the form of the chemical used at the site is known, and information on the absorption of that chemical form is available, the intake equation can be modified to account for a specific absorption.

4.4.5.2.5 The medium in which the chemical is contained also can affect the degree of bioavailability. This is most pronounced in media that demonstrate an ability to bind chemicals (such as soil and sediments). When ingested or inhaled into the body, a competition occurs between retention of the chemical on the medium and absorption of the chemical into the body. Therefore, some of the chemical may be excreted from the body without having been absorbed and some may have been absorbed and available to exert an effect. Many factors can influence the degree to which the medium will bind the chemical, most of which cannot be reliably predicted (for example, nature of the medium [organic carbon or clay content, particle size], other chemicals being absorbed, pH, organ condition, etc.). In some instances, information may be available on the degree to which a particular medium affects specific absorption routes, and the equation can be modified to account for these influences.

4.4.5.2.6 In most assessments, it is assumed that the chemical concentrations remain constant over time, often for as long as 30 years. In many cases, this assumption will not be valid. Chemical concentrations are usually

reduced over time by degradation, migration, dilution, volatilization, or other removal processes. If the appropriate site-specific characteristics for natural attenuation (e.g., soil properties, climate, pH, grain size, etc.) are known and can be quantified, a concentration that decreases over time can be derived for assessing intakes through modeling.

4.4.5.3 **Assessment of Uncertainties.** At the conclusion of the exposure assessment, the uncertainties associated with the estimation of chemical intake should be summarized. The basis for the uncertainty should be identified (e.g., use of a default parameter), the degree of the uncertainty qualitatively estimated (low, medium or high), and the impact of the uncertainty stated (overestimate and/or underestimate).

4.5 TOXICITY ASSESSMENT

4.5.1 **Objectives.** The toxicity assessment fulfills two objectives in a risk assessment. First, it results in the selection of appropriate toxicity values to use in generating estimates of potential health risks associated with chemical exposure. This is accomplished by identifying appropriate sources of toxicity values and reviewing the available information to identify the most appropriate values to use. Second, the toxicity assessment forms the basis for developing summaries of the potential toxicity of the COPCs for inclusion in the risk assessment. This is accomplished by reviewing the available information on the toxicity of the COPCs and summarizing the factors pertinent to the exposures being assessed.

4.5.2 **Derivation of Toxicity Values.** Most toxicity values applied to risk assessments have been developed by EPA and generally do not need to be developed by the risk assessor. However, to appropriately select and use toxicity values, and to identify assumptions and uncertainties associated with them, an understanding of the development is needed. For a complete discussion of this procedure, see RAGS (USEPA, 1989j).

4.5.3 Toxicity Assessment for Carcinogenic Effects.

4.5.3.1 The toxicity value used to describe a chemical's carcinogenicity is the cancer slope factor (SF). Two types of SFs are available: oral SFs and inhalation SFs,

and are expressed in terms of $(\text{mg/kg-dy})^{-1}$. EPA's Human Health Assessment Group reviews the SFs developed by different EPA program offices to reach an agency consensus on the value and to verify the SF.

4.5.3.2 In addition to the numerical value, each potentially carcinogenic chemical is assigned a "weight of evidence" category, expressing the likelihood that the chemical is a human carcinogen. Six categories exist (A, B1, B2, C, D, and E). In general, carcinogenic assessments are performed for chemicals in groups A, B1, B2, and on a case-by-case basis in group C.

4.5.4 Toxicity Assessment For Noncarcinogenic Effects.

4.5.4.1 Chemicals that cause toxic effects other than cancer such as organ damage, physiological alterations, and reproductive effects are generically grouped as noncarcinogens. These types of toxicants share one point in common in regard to their effects: the apparent occurrence of a toxicological threshold. This threshold is an exposure level that must be exceeded for the adverse impact of the chemical to manifest itself. Below this threshold, factors such as the body's protective mechanisms (e.g., metabolism, elimination) can limit the chemical effects, preventing the expression of adverse effects. The basis of the derivation of noncarcinogenic toxicity values, then, is to identify this threshold level, and modify it to express potential human toxicity.

4.5.4.2 The toxicity descriptor most commonly used in risk assessments for describing a chemical's noncarcinogenic toxicity is the reference dose (RfD) or reference concentration (RfC). An RfD or RfC "is a provisional estimate (with uncertainty spanning perhaps several orders of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime, in the case of a subchronic RfD or RfC, or during a lifetime, in the case of an RfD or RfC" (USEPA, 1992e).

4.5.4.3 Several types of RfDs are available:

- Chronic RfDs, used to assess chronic exposures (greater than 7 years [one-tenth of a lifetime]). Two different types of chronic RfDs are available: oral

RfD_o and inhalation RfD_i. More recently, RfCs have been developed for the inhalation route.

- Subchronic RfD_s, for exposures between 2 weeks and 7 years. Both oral and inhalation subchronic RfDs (RfD_{so} and RfD_{si}, respectively) may be available.
- Developmental RfD_{dt}, used to evaluate potential effects on a developing organism following a single exposure event (very few have been developed).

4.5.4.4 EPA's RfD workgroup reviews and verifies existing chronic RfDs and develops new RfDs, and resolves conflicting toxicity values developed within the EPA in the past. The RfD workgroup also states the degree of confidence associated with the study, the database, and the RfD (low, medium, or high). Subchronic RfDs are not reviewed or verified and are, therefore, considered unverified values. These values should only be used when chronic RfDs are not available.

4.5.5 Sources of Toxicity Values.

4.5.5.1 Several sources of up-to-date toxicity values and supplementary information are available. These sources are presented below. A hierarchical approach is recommended when consulting these sources: if information is not available through the first source, the second should be consulted, and so forth.

- Integrated Risk Information System (IRIS). This is EPA's primary database for the reporting of up-to-date toxicity values that have been verified by the EPA. IRIS may be accessed through the Internet at <http://www.epa.gov/ngispgm3/iris/index.html>. IRIS contains chemical profiles that present verified chronic RfDs, chronic RfCs, and cancer SFs. The study(s) from which the toxicity value was derived is summarized, and the method of derivation is explained (e.g., applied uncertainty and modifying factors, level of confidence, extrapolation model). Supplementary toxicity information is also sometimes included. In addition, some IRIS files contain regulatory information (such as the SDWA Maximum Contaminant Levels [MCLs] and CWA Ambient Water Quality Criteria), and often

chemical and physical properties, synonyms, and other information.

- Health Effects Assessment Summary Tables (HEAST). This document is published annually by EPA and is a collection of interim and provisional toxicity values developed by EPA. Verified toxicity values are not presented in the most current version of HEAST, rather, the user is directed to IRIS. HEAST can be obtained through the National Technical Information Service (NTIS).
- EPA's Superfund Health Risk Technical Support Center (513-569-7300). Assistance may be requested from these offices on the existence of provisional toxicity values not presented in either IRIS or HEAST or on other factors relating to risk assessment. However, EPA only provides services for sites being managed under the Federal Superfund Program.
- For sites other than Superfund, the USACE user is directed to contact the appropriate DOD Toxicology and Research Program offices: USACHPPM Toxicology Directorate at: <http://chppm-www.apgea.army.mil/tox/program.htm>, then contact the Health Effects Research Program Manager; or contact the Air Force Research Laboratory, Human Effectiveness Directorate, Operational Toxicology Division at: <http://voyager.wpafb.af.mil> or (937) 255-5150 x3105.

4.5.5.2 Additional information on the toxicity of the chemicals can be found in the following general sources:

- EPA criteria documents such as those regarding drinking water, ambient water, and air quality, as well as health effects assessment documents.
- Toxicological Profiles developed by ATSDR.

4.5.6 Use of Toxicity Values. Toxicity values developed by EPA can generally be used directly in a risk assessment with few or no modifications. The mechanism for combining toxicity values with exposure or intake estimates is described in Section 4.7. However, there are a number of factors that should be considered

when applying these toxicity values. These are discussed in the following paragraphs.

4.5.6.1 Absorption Considerations. Most toxicity values are based on administered, rather than absorbed, doses, and the absorption efficiency has not been considered. However, whatever absorption has occurred during the toxicological study is usually inherent in the toxicity value. Therefore, use of a toxicity value assumes that the extent of absorption observed in the study is also appropriate for the exposure pathway being assessed. Differences in absorption efficiencies between that applicable to the toxicity value and that being assessed may occur for a number of reasons. Two factors that will influence absorption efficiencies are differences in chemical form and differences in the exposure medium.

4.5.6.2 Use of Oral Toxicity Values for Assessment of Dermal Exposure Route. EPA does not generate toxicity values for dermal exposures. As a surrogate, oral toxicity values are applied to the assessment of dermal exposures. However, since dermal intakes are based upon absorbed doses and most oral toxicity values are based upon administered doses, the oral toxicity value may be modified before using in a dermal assessment. For a complete discussion of this procedure, when it should be used, and the appropriate procedures for its application, see Appendix A of RAGS (USEPA, 1989j).

4.5.7 Special Chemicals. Some chemicals commonly detected at a site require a specific methodology to generate a toxicity value or are reported in a manner that influences the toxicity value. The following chemicals are discussed relative to these special circumstances:

- Lead.
- PAHs.
- Polychlorinated biphenyls (PCBs).
- Chlorinated dibenzo-p-dioxins and dibenzofurans (CDDs/CDFs).
- Total petroleum hydrocarbons (TPH) and other petroleum groupings.

- Military unique chemicals.

4.5.7.1 Toxicity Values for Lead.

4.5.7.1.1 Lead is a unique chemical in its pharmacokinetic and toxicological properties. Although classified as both a potential carcinogen (B2 weight of evidence) and a noncarcinogen, lead is most often assessed as a noncarcinogen only, since these effects manifest themselves at doses lower than those for carcinogenicity. However, in contrast to the assumption of the existence of a threshold for noncarcinogenic responses, there does not appear to be a threshold below which lead does not elicit a response. For these reasons and others (including lead's propensity to accumulate in bone tissue), the use of blood lead (PbB) levels, rather than chronic daily intakes, is the best indicator of potential adverse impacts). EPA has not developed a noncarcinogenic RfD or a carcinogenic SF for lead.

4.5.7.1.2 EPA has developed an exposure model for lead that considers both its biokinetics and toxicological properties. The IEUBK model (Pub. #9285.7-15-2, PB93-963511) is available through NTIS. The model integrates the intake of lead from multiple sources, including soil, food, and water ingestion, inhalation, and, when appropriate, maternal contributions. Intakes are assessed for children from the ages 0 (birth) to 7. The model does not assess lead intakes for older children or adults. Childhood exposure to lead is the focus of this assessment because this receptor group is recognized as the most sensitive to the noncarcinogenic effects of lead.

Use of the EPA'S IEUBK Model for Lead Exposures Should be Limited to Residential, Childhood Exposures Only.

Where adult and/or non-residential exposures are expected, a more appropriate model should be used. See *Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil* (USEPA, 1996c).

4.5.7.1.3 The IEUBK model integrates intakes of lead from multiple exposure routes and predicts a PbB level,

in $\mu\text{g/dL}$, at different ages (up to 7 years of age). The maximum predicted PbB level can then be compared with a threshold level of $10 \mu\text{g/dL}$, which EPA has adopted as an “acceptable” PbB level.

4.5.7.1.4 Use of the IEUBK model is recommended when children of this age group are anticipated to be receptors at a site. However, when adults are the only potential receptors, the EPA’s Technical Review Workgroup for Lead has developed an interim approach for evaluating adult soil lead exposure. *Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil* (USEPA, 1996c) provides the currently accepted methodology. This interim guidance is available on the Internet at: http://www.epa.gov/superfund/oerr/ini_pro/lead.

4.5.7.2 Toxicity Values for PAHs.

4.5.7.2.1 PAHs, also known as polynuclear aromatic hydrocarbons or polynuclear aromatics, are a class of compounds containing hydrogen and carbon in multiple ring structures. There are numerous possible PAH molecules, many of which are commonly analyzed for in a semivolatile chemical analysis.

4.5.7.2.2 PAHs are a natural component of petroleum and are found in heavier petroleum fractions such as lube oil, naphtha, jet fuel, etc. PAHs are also produced by the incomplete combustion of organic matter, and are created during fires, volcanoes, combustion of gasoline, burning of wood, etc. For these reasons, PAHs are ubiquitous in the environment at low levels, particularly in soil and sediments, to which they readily bind.

4.5.7.2.3 Some PAHs are classified by EPA as potential human carcinogens, including:

- Benzo(a)anthracene.
- Benzo(a)pyrene.
- Benzo(b)fluoranthene.
- Benzo(k)fluoranthene.

- Chrysene.
- Dibenzo(a,h)anthracene.
- Indeno(1,2,3-cd)pyrene.

4.5.7.2.4 EPA has developed a cancer SF for one carcinogenic PAH only: benzo(a)pyrene. However, comparative toxicity values have been proposed for the other carcinogenic PAHs that describe the toxicity relative to the toxicity of benzo(a)pyrene. Several sets of comparative toxicity values have been proposed. The EPA’s *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons* (USEPA, 1993b) should be consulted for Toxicity Equivalence Factors (TEFs) to utilize in this assessment.

4.5.7.2.5 Other PAHs are considered by EPA to be noncarcinogens; however, only a few of these currently have RfDs. Currently, there is no comparative toxicity approach for estimating the toxicity of noncarcinogenic PAHs that do not have RfDs.

4.5.7.3 Toxicity Values for PCBs.

4.5.7.3.1 PCBs are a group of chlorinated compounds based on the biphenyl molecule. There are 209 possible individual congeners of PCBs, differing in the degree and location of chlorination. PCBs are seldom analyzed as individual compounds; rather, they are commonly analyzed as total PCBs, Aroclor compounds (a commercial mixture, with Aroclor™ being Monsanto’s trade name) or sometimes in congener groups (such as tetrachlorobiphenyls or pentachlorobiphenyls). When analyzed as Aroclors, the results are expressed relative to different commercial mixtures of Aroclor, such as Aroclor 1248, Aroclor 1254, or Aroclor 1260.

4.5.7.3.2 The toxicity values (cancer SF and RfD) developed for PCBs are based on specific Aroclor mixtures -- the SF is based on Aroclor 1260 and the RfD of Aroclor 1016. These values are used to assess the potential impacts of PCBs reported in any form (i.e., another Aroclor mixture or total PCBs). However, it is known that the toxicity of PCBs varies between these congeners. Most notably, the carcinogenic potency is less in smaller molecular weight chlorinated biphenyls. Therefore, application of the Aroclor 1260 cancer SF to

Aroclor 1232 or 1248 mixtures may overestimate the degree of health risk posed by the PCB.

4.5.7.3.3 EPA recommends the use of a tiered approach to the evaluation of PCB carcinogenicity, even though toxicity values for the different Aroclors are still available. Information on the application of this procedure can be found on the IRIS database, accessible on the Internet at:

<http://www.epa.gov/ngispgm3/iris/index.html>.

4.5.7.4 Toxicity Values for CDDs/CDFs.

4.5.7.4.1 CDDs/CDFs, often abbreviated “dioxins and furans,” are a group of chlorinated compounds based on the dibenzo-p-dioxin or dibenzofuran molecule (both of which are structurally similar). CDDs/CDFs are not compounds used for commercial purposes in the past, and, outside of research, have no known use. Rather, CDDs/CDFs are byproducts of high temperature combustion of chlorinated compounds and impurities in other chemical products such as pentachlorophenol or PCBs. Although not considered a “natural” product, some forms of CDDs and CDFs (specifically octa-CDD and octa-CDF) are ubiquitous in the environment at very low concentrations.

4.5.7.4.2 There are 75 possible CDD congeners and 135 possible CDF congeners. As with PCBs, the degree of toxicity varies with the degree and location of the chlorine atoms on the hydrocarbon ring, becoming higher when the 2, 3, 7, and 8 positions of the molecule have chlorine atoms. Considered the most potent CDD, 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) is the reference against which all other CDDs and CDFs are compared.

4.5.7.4.3 Analysis of CDDs and CDFs is most commonly reported by congener group (i.e., as either tri-, tetra-, penta-, hexa-, hepta-, or octachlorodibenzo-p-dioxin or -dibenzofuran). Within these groups the results are often further separated into “2,3,7,8- substituted” or “other” categories. This form of reporting is needed to appropriately assess CDDs and CDFs. Reporting as “total dioxins” or even just by congener group may require the assumption that all CDDs/CDFs present are as toxic as 2,3,7,8-TCDD, resulting in an overestimate of potential health risks posed by the presence of CDDs/CDFs.

4.5.7.4.4 A toxicity value (cancer SF) is available for 2,3,7,8-TCDD. As a policy, EPA has developed a TEF approach for other CDDs/CDFs, wherein the toxicities of these other compounds are expressed relative to the toxicity of 2,3,7,8-TCDD. These values can be used to express the amount of CDDs/CDFs present in a sample as “2,3,7,8-TCDD equivalents.” Further discussion of the TEFs for CDDs/CDFs can be found in USEPA, 1989d.

4.5.7.5 Toxicity Values for TPHs and Other Petroleum Groupings.

4.5.7.5.1 Use of chemical-specific data to derive an estimate of potential health risks is the recommended method of performing a BRA. Use of chemical groupings such as TPH is less than optimal, since these types of chemical groupings vary in their chemical composition and, hence, toxicity.

4.5.7.5.2 Some attempts have been made to derive toxicity values for TPH. However, since the composition of TPH varies from place to place (even within the same site) with the age of the spill, and the type of fuel spilled or disposed, it is unlikely that these estimates are valuable descriptors of the potential toxicity of the components comprising the TPH detection.

4.5.7.5.3 For some other chemical groupings, toxicity tests have been performed on the specific mixture, and adequately describe the toxicity of the chemical grouping, such as jet fuel and diesel fuel. One potential pitfall to using these values is that the RfD may represent the toxicity of the mixture when fresh, but may not represent the toxicity of the mixture after release to the environment. When released, processes such as biodegradation, chemical migration, and transport may alter the composition of the mixture, making it more concentrated in some compounds and less concentrated in others. In these instances as well, chemical-specific analysis of the media is preferred.

4.5.7.6 Toxicity values for Military Unique Chemicals. Many DOD sites contain potentially toxic chemicals not commonly found except on military sites. Military unique chemicals may include explosives, rocket fuels, radioactive materials, chemical agents, or degradation products of these compounds. Because of the unique status of many military compounds, EPA is often unable to supply toxicity information. Toxicity information can

usually be obtained by contacting the USACHPPM Toxicology Directorate at:
<http://chppm-www.apgea.army.mil/tox/program.htm>, then contact the Health Effects Research Program Manager.

4.6 RISK CHARACTERIZATION

4.6.1 Objective. In the risk characterization, the chemical intakes estimated in the exposure assessment are combined with the appropriate critical toxicity values identified in the toxicity assessment. The results are the estimated cancer risks and noncarcinogenic health hazards posed by the exposures. Along with the numerical estimates of potential health risks and hazards, a narrative describing the primary contributors to health risks and hazards and factors qualifying the results are presented.

4.6.2 Methodology. In the following paragraphs, the methodology is presented for performing the quantitative risk characterization for carcinogens, followed by the methodology for noncarcinogens. These are discussed separately because different methodologies are used for each of these classes of chemicals.

4.6.2.1 Carcinogenic Risks. The objective of a risk characterization for carcinogenic chemicals is to derive an estimate of the overall cancer risk associated with exposure to all potential carcinogens at a site through all routes of exposure for a given receptor group, for both CT and RME current and future use scenarios. To derive this value, the cancer risk associated with exposure to a single carcinogen through a single exposure pathway is estimated. These single chemical risk estimates are then combined (added) within a pathway to describe the risk associated with a given pathway. Pathway-specific risks are then combined (added) for all exposure pathways for a given receptor group to derive an overall risk estimate for each of the cases.

4.6.2.2 Noncarcinogenic Hazards.

4.6.2.2.1 The objective of a risk characterization for noncarcinogenic chemicals is to compare the estimated chemical intake of one chemical through one exposure route with the “threshold” concentration; that is, the

level of intake that is recognized as unlikely to result in adverse noncarcinogenic health effects (i.e., the RfD). The comparison of estimated intake and acceptable exposure level is called a hazard quotient (HQ).

4.6.2.2.2 An HQ of 1 indicates that the estimated intake is the same as the RfD, whereas an HQ greater than 1 indicates the estimated intake exceeds the RfD. No further conclusions can be drawn as the relationship between intake and toxicity used to derive the RfD is not linear. In contrast to cancer risk estimates, HQs can range from values less than 1 to greater than 1.

4.6.2.2.3 To examine the potential for the occurrence of adverse noncarcinogenic health effects as a result of exposure to multiple noncarcinogens through multiple exposure pathways (for each of the exposure scenarios; current-future for average and upper bound exposures), it is assumed that an adverse health effect could occur if the sum of the HQs exceeds 1. In other words, even if exposure to each individual chemical is below its RfD (HQ less than 1), if the sum of the ratios for multiple chemicals exceeds unity, adverse health effects could occur.

4.6.2.2.4 Applying the assumption of additivity is considered to be a conservative approach, but may overestimate or underestimate the actual potential health risk presented by the exposure. If the overall hazard index (HI) is greater than unity, consideration should be given to the known types of noncarcinogenic health effects posed by exposure to the chemicals. If the assumption of additivity is not valid (i.e., if the chemicals most strongly contributing to the exceedance of the HI display very different types of noncarcinogenic effects) the HI may be segregated according to toxicological endpoint. These segregated HIs may then be examined independently.

4.6.2.2.5 Factors that need to be considered in segregation of endpoints include the critical toxicological effect upon which the toxicity value is based, as well as other toxicological effects posed by the chemical at doses higher than the critical effect. Major categories of toxic effects include neurotoxicity, developmental toxicity, immunotoxicity, reproductive toxicity, and individual target organ effects (hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, dermal, and ocular) (USEPA, 1989j).

4.7 EVALUATION OF UNCERTAINTIES AND LIMITATIONS

4.7.1 Objective.

4.7.1.1 EPA has identified two requirements for full characterization of risk. First, the characterization must address qualitative and quantitative features of the assessment. Second, it must identify any important uncertainties in the assessment. Methods of identifying and describing uncertainties in a risk assessment are discussed below.

4.7.1.2 According to recent guidance (USEPA, 1992d):

“EPA risk assessors and managers need to be completely candid about confidence and uncertainties in describing risks and in explaining regulatory decisions. Specifically, the Agency's risk assessment guidelines call for full and open discussion of uncertainties in the body of each EPA risk assessment, including prominent display of critical uncertainties in the risk characterization. Numerical risk estimates should always be accompanied by descriptive information carefully selected to assure an objective and balanced characterization of risk in risk assessment reports and regulatory documents.”

4.7.1.3 Identification and discussion of uncertainty in an assessment is important for several reasons (USEPA, 1991a):

- Information from different sources carries different kinds of uncertainty, and knowledge of these differences is important when uncertainties are combined for characterizing risk.
- Decisions must be made on expending resources to acquire additional information to reduce uncertainties.
- A clear and explicit statement of the implications and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.
- Uncertainty analysis gives the decision-maker a better understanding of the implications and limitations of the assessments

4.7.2 Sources of Uncertainty. Sources of uncertainty exist in almost every component of the risk assessment. Overall, uncertainties can arise from two main sources: variability and data gaps. Uncertainty from variability can enter a risk assessment through random or systematic error in measurements and inherent variability in the extent of exposure of receptors. Uncertainty from data gaps is most prominently seen when approximations are made regarding exposures, chemical fate and transport, intakes, and toxicity. Specific sources of uncertainty in a risk assessment are identified and discussed below. Following this discussion, different approaches for conducting an uncertainty evaluation are presented.

4.7.2.1 Uncertainties Associated with Sampling and Analysis.

4.7.2.1.1 The identification of the types and numbers of environmental samples, sampling procedures, and sample analysis all contain components that contribute to uncertainties in the risk assessment. Decisions regarding the scope of sampling and analysis are often made based on the CSM developed at the planning stages of the investigation. While appropriate planning may minimize the uncertainty associated with these components, some uncertainty will always exist, and cannot always be reduced realistically, rather it may be sufficient to just understand the degree of uncertainty associated with the assessment.

4.7.2.1.2 Some of the assumptions in this component that contribute to uncertainty in the assessment include:

- Media sampled. Due to budget limitations, only representative areas of the site are selected for sampling and analysis. This selection is usually based upon the anticipated presence of a chemical in a medium from the site history and the chemical's chemical and physical properties. If all areas of the site in which a chemical is present have not been sampled, small incremental risks either less than or equal to the risk accounted for in the BRA may not be described, although this approach is usually not feasible.
- Locations sampled. The type of sampling strategy selected may impact the uncertainty associated with the results. For example, purposive sampling (sampling at locations assumed to contain the

chemicals) will likely result in a higher frequency of chemical detection and concentration than random sampling or systemized grid sampling. Therefore, use of the results may skew the assessment toward greater assumed exposures.

- Number of samples. Fewer samples result in a higher degree of uncertainty in the results. This is demonstrated in the summary statistics, specifically the 95% UCL, in which the statistical descriptor ("t" or "H" value), and hence the 95% UCL, increases with a lesser number of samples. Planning for a specific number of samples to reach a specific degree of statistical confidence can limit the degree of uncertainty, although reduction may not be feasible and quantifying the uncertainty may be just as effective in defining risks.
- Sampling process. The sampling process itself can contribute to uncertainties in the data from a number of factors, including sampling contamination (cross-contamination from other sample locations, introduction of chemicals used in the field), poorly conducted field procedures (poor filtering, incomplete compositing), inappropriate sample storage (head-space left in containers of volatile sample containers, inappropriate storage temperatures), sample loss or breakage, and other factors. Some of these factors can be controlled by an adequate SAP; however, planning does not prevent the occurrence of sampling errors.
- Analytical methodology. The analytical methodology can contribute to uncertainty in a number of ways, including the chemicals analyzed (if analyses of all important chemicals were not performed), the DLs or QLs applied (if not sufficient), limitations in the analysis due to matrix effects, chemical interferences, poorly conducted analyses, and instrumentation problems. Some of these factors can be addressed in up-front planning (such as selection of the analytical method), others cannot (instrumentation problems) be mitigated.

4.7.2.2 Uncertainties Associated with Selection of COPCs. Evaluation of the data to select COPCs for the risk assessment may result in uncertainties. Application of selection criteria may inadvertently result in an inappropriate exclusion or inclusion of chemicals as

COPCs. Improper inclusion or exclusion of chemicals can result in an underestimation (if inappropriately removed) or overestimation (if inappropriately retained) of potential health risks. Uncertainties associated with the selection criteria include the following:

- Background comparison. If background measurements are not truly representative of background conditions, chemicals may be inappropriately retained or removed from the list of COPCs.
- Sample contamination. Uncertainty in the assessment can occur if chemicals are not recognized as being present as a result of sampling or laboratory introduction and are included as COPCs.
- Frequency of detection. Use of detection frequency as a selection criterion may result in the inappropriate exclusion of chemicals as COPCs.

4.7.2.3 Uncertainties Associated with the Exposure Assessment. Exposure estimates are associated with a number of uncertainties that relate to the inherent variability of the values for a given parameter (such as body weight) and to uncertainty concerning the representativeness of the assumptions and methods used.

- Potential exposure pathways. Potential exposure pathways are identified by examining the current and future land uses of the site and the fate and transport potential of the COPCs. While current land use and potential exposure pathways are often easy to identify, potential future uses can only be inferred from information available. For these reasons, sometimes the most conservative potential future land use (i.e., residential) is often assumed in many assessments to avoid underestimating potential health risks. This and any assumption regarding future land use and exposure pathways will add uncertainty to the assessment.
- Potentially exposed receptors. As discussed above, identification of potentially exposed receptors is based upon information currently available. Assumed exposed receptors under future use scenarios can only be obtained from census projections, land planning, and ownership records and can add uncertainty to the assessment.

- Exposure and intake factors. Point values for exposure estimates are commonly used in risk assessments rather than a distribution of exposure values that describe the distribution of exposures. These values are usually conservative, and their use results in introduction of conservatism into the risk assessment. Conversely, use of average (CT) and the upper end (RME) exposure and intake factors describing a range of exposures may reduce this conservativeness. Additionally, selection of site-specific exposure and intake factors will lessen the uncertainty to some degree, but since not all potentially exposed receptors will be exposed to the same degree, uncertainty cannot be eliminated.
- Exposure point concentrations. Exposure point concentrations are derived from measured site media chemical concentrations alone and fate and transport modeling. With regard to estimating exposure point concentrations from sampling data alone, use of 95% UCL and mean concentrations is associated with some degree of uncertainty. The 95% UCL is used to limit the uncertainty of estimating the true mean concentration from the sample mean concentration. This value may overestimate the true mean concentration. Use of the sample mean concentration may under- or overestimate the true mean concentration. Therefore it is strongly recommended that both values are used to represent a range of exposure point concentrations the population could potentially be exposed to at the site.
- Application of fate and transport modeling adds an additional tier of potential uncertainty to exposure point estimates. Models cannot predict “true” exposure point concentrations at different times and places or in different media, but provide an estimate of the potential concentration under certain assumptions. Often, the assumptions used in the models are conservative to avoid underestimating potential concentrations. In addition, not all applicable processes are or can be considered (e.g., degradation, removal processes). However it is even more conservative to use current detected concentrations for exposure point concentrations for future use scenarios.

4.7.2.4 Uncertainties Associated with Toxicity Assessment. EPA-derived toxicity values are recommended to be used in risk assessments. These values are developed by applying conservative assumptions and are intended to protect even the most sensitive individuals in the populations potentially exposed. Use of these values will almost always result in overestimates of potential risk. Factors that contribute to uncertainty include:

- Use of uncertainty factors and modifying factors (MFs) in the RfD. Noncarcinogenic RfDs are primarily derived from animal toxicity studies performed at high doses to which UFs or MFs (each usually a factor of 10) are applied. This process may remove the derived dose many orders of magnitude from the dose which caused the critical effect in the study, and will most likely overestimate the site risks.
- Use of an “upper bound” cancer SF. The SF is often derived from high dose animal studies and extrapolated to low doses using extrapolation models. The 95% UCL of the slope predicted by the extrapolation model is adopted as the SF. Use of this value results in an upper bound estimate of potential risks.
- Choice of study used to derive toxicity value. The inclusion or exclusion of studies by EPA in the derivation of a toxicity value is usually made by professional judgment and affects the numerical toxicity value.
- The assumption of human sensitivity. When deriving RfDs and SFs, EPA selects a critical study (usually the animal study showing an adverse effect at the lowest exposure or intake level) as the basis for deriving the RfD or SF. EPA assumes that humans are at least as sensitive as the most sensitive animal study.

4.7.2.5 Uncertainties Associated with Risk Characterization. EPA's standard algorithms are commonly used to calculate chemical intakes and associated health risks and hazards. There are certain assumptions inherent in use of these equations that add uncertainty to the assessment.

- Assumption of additivity. Calculation of both carcinogenic risks and noncarcinogenic hazards assumes (at least as a first-line approach) additivity of toxic effects. This assumption adds uncertainty to the assessment and may result in an overestimate or underestimate of potential health risks, depending on whether synergistic or antagonistic conditions might apply.
- Omission of certain factors. The standard algorithms (without modification) do not consider certain factors, such as absorption or matrix effects. In cases where these processes are important, use of the standard algorithms without modification may result in an overestimate of potential chemical intakes.

4.7.3 Evaluation of Uncertainty. Various approaches can be applied to describe the uncertainties of the assessment, ranging from descriptive to quantitative. The method selected should be consistent with the level of complexity of the assessment. It may be appropriate to conduct an in-depth quantitative evaluation of uncertainty for a detailed, complex assessment, but may not be appropriate or even needed for a screening level or relatively simple assessment. Qualitative and quantitative approaches to expressing uncertainty are discussed below.

4.7.3.1 Qualitative Evaluation. A qualitative evaluation of uncertainty is a descriptive discussion of the sources of uncertainty in an assessment, an estimation of the degree of uncertainty associated with each source (low, medium, high), and an estimate of the direction of uncertainty contributed by that source (under or overestimation). A qualitative uncertainty assessment does not provide alternate risk or hazard values, but does provide a framework in which to place the risk and hazard estimates generated in the assessment.

4.7.3.2 Quantitative Evaluation.

4.7.3.2.1 A quantitative uncertainty assessment is any type of assessment in which the uncertainty is examined quantitatively, and can take several forms. A sensitivity analysis is a form of uncertainty analysis in which the specific parameters are modified individually from which the resultant alternate risks and hazard

estimates are derived. Probabilistic approaches, such as MC simulations, are a more complex form of uncertainty analyses, and examine the effect of uncertainty contributed by a number of parameters.

4.7.3.2.2 A sensitivity analysis is a process of changing one variable while leaving the others constant and determining the effect on the output. These results are used to identify the variables that have the greatest effect on exposure. This analysis is performed in three steps:

- Define the numerical range over which each parameter varies.
- Examine the relative impact that each parameter value has on the risk and hazard estimates.
- Calculate the approximate ratio of maximum and minimum exposures obtained when range limits for a given parameter are applied to the risk algorithm.

4.7.3.2.3 A probabilistic uncertainty analysis, such as the MC simulation, examines the range of potential exposures associated with the distribution of values for input parameters of the risk algorithm. Such methods can allow the risk assessor to estimate both the uncertainty and variability associated with various parameters of a risk assessment. Uncertainty in these terms is defined as “a lack of knowledge about specific factors, parameters, or models” and variability as “observed differences attributable to true heterogeneity of diversity in a population or exposure parameter” (USEPA, 1997a).

In a probabilistic analysis, probability density functions are assigned to each parameter, then values from these distributions are selected and inserted into the exposure equation. After this process is completed a number of times, a distribution of predicted values is generated that reflects the overall uncertainty of inputs to the calculation. The results are presented graphically as the cumulative exposure probability distribution curve. In this curve, the exposure associated with the 50th percentile of the exposure may be viewed as the “average” exposure and those associated with the 90th or 99.9th percentile may be viewed as “high end” exposure.

4.7.3.2.4 An MC simulation is performed in four steps:

EM 200-1-4
31 Jan 99

- Assign probability distribution functions to selected parameters in the risk algorithm.
- Develop distributions for the selected parameters (if not already available) and identify a number of randomly chosen values within that distribution.
- Apply the random input values for the parameters to the risk algorithm, and generate a number of randomly generated output values.
- Develop a cumulative probability distribution curve from the randomly generated output values.

computer-based proprietary programs are available to conduct this simulation.

4.7.3.2.5 A tiered approach should be used to determine the complexity, cost, and time that the project warrants for the probabilistic analysis, and whether one needs to be performed at all. Results from a traditional deterministic risk assessment should be examined prior to performing a probabilistic analysis. If the risk is close to the level of concern, the project may benefit from a probabilistic analysis. If the site clearly requires, or does not require action, further analysis is likely not necessary. The risk assessor should discuss the insight to the risk estimate that could be derived from further analysis with the risk manager as they need to be balanced with costs and time that the analysis will require.

4.7.3.2.6 A sensitivity analysis should be performed on the results of the deterministic risk assessment to determine which parameters should be focussed upon in the probabilistic assessment. To effectively utilize resources, those parameters whose uncertainty or variability has the greatest impact on the risk estimate should be assigned probability distributions in the MC simulation, other less important parameters may be held constant.

4.7.3.2.7 For more information on probabilistic analysis, including recommendations for reporting requirements, consult the *Guiding Principles for Monte Carlo Analysis* (USEPA, 1997a) or access the EPA's web site at:

<http://www.epa.gov/nceawww1/mcpolicy.htm>. Additionally, EPA is in the process of developing RAGS Part E, *Supplemental Guidance to RAGS: The use of Probabilistic Analysis in Risk Assessment*. Several